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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,778	09/08/2005	Helmut Haning	Le A 36111	7455

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EXAMINER
WEBB, WALTER E

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,778	HANING ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Unless specifically repeated/maintained *infra*, all previous rejections or objections are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, is maintained with regard to claims 1, 5, 6, and 11 since applicant claims a **cure** for cancer, ALS, and MS. The previous arguments with regard to ALS and MS for the prophylaxis of these diseases apply here again where applicant is claiming a cure. Curing and prophylaxis have the same meaning and thus the same argument for lack of enablement applies to both. There are other diseases such as cancer that were not considered in the previous action, which the applicant has currently amended. While the cure for the other diseases listed in the markush group of claim 1 are met with a great deal of skepticism, and thus are equally lacking in enablement, the examiner will focus on the cure of cancer.

The specification, with regard to the terms “prophylaxis” or “cure” is inadequate. These terms were not described in the specification in such a way as to enable one skilled in the art to which it pertains. Applicant’s provides no data evidencing a cure for

cancer or any other disease. In order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering the presently claimed active agent, all cancers with any degree of sensitivity whatsoever to such an agent could be cured. However, such a situation is sufficiently unusual. No reasonable scientific basis as been provided to enable the artisan to reasonably a cure for cancer by simply administering the claimed active agent.

The specification is also inadequate in regard to the breadth of the conditions claimed. In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that the treatment or cure of cancers in general could be effectively achieved by the administration of the claimed active agent. Based on the state of the art, as discussed below, the artisan would have only accepted that the treatment of a specific type of cancer could be achieved, rather than that such an agent could have been used to treat any cancer type.

The specification fails to direct the artisan as to which cancers are known to be sensitive to such a composition or how one would even go about determining the subset of cancers that would have been reasonably expected to have such sensitivity, especially in consideration of the highly complex nature of cancer.

The objective truth that cancer of any type may be treated is doubted because, while the state of the art of cancer treatment is well developed with regard to the treatment of specific cancer types (see Rubin et al., “Principles of Cancer Treatment: Management of Cancer Cases.” ACP Medicine Online,

http://www.medscape.com/viewarticle/534498), the state of the art with regard to treating or curing cancer in general is grossly underdeveloped.

In this regard, Rubin et al. is cited. In particular, there is no known anticancer agent or combination of anticancer agents that is effective against treating all cancer types, nor is there any known anticancer agent or combination of agents that is effective against inhibiting the growth of any type of cancer cell. The Rubin reference clearly shows that for the various known cancer types, there is not one specific chemotherapeutic agent or combination thereof that is effective at treating cancer or inhibiting the growth of cancer cells for each and every type of cancer (see Treatment, pp 2-3.).

Given that there was not known any specific agent or combination of agents effective to treat all known types of cancer, one of ordinary skill in the art would not accept on its face Applicant's statement that such an objective could be achieved in any cancer type. The artisan would have required sufficient direction as to which specific types of cancer could be effectively treated with the presently claimed combination of active agents and, further, how the artisan could predict what particular types of cancer would actually show sensitivity to the presently claimed composition such that the artisan would have been imbued with at least a reasonable expectation of success in treating the cancer. Such success would not have been reasonably expected for all cancer types given the highly complex and variable nature of all cancers known in the art and that the treatment of all known cancer types would have been an outcome not reasonably expected by one of ordinary skill in the art. To the artisan, the concept of a

single agent, or even a combination of agents, that is effective to treat all known types of cancer would have been unique and, thus, met with a great deal of skepticism.

The Examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02). However, in light of the state of the art, which recognizes the unpredictable nature of human cancer, there is no apparent disclosure to support the contention that the use of the claim specified active agents could actually effectively treat a cancer of any known type in a synergistic manner by simply administering, by any method, an amount of the claimed active agent, since the present specification fails to enable one of ordinary skill in the art to practice the entirety of the presently claimed invention.

Practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that treatment or cure of cancer of any type could be achieved with the presently claimed active agent. In order to actually achieve such an objective, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicant has failed to demonstrate, via direct evidence or sound reasoning, that all types of human cancer could actually be treated with the presently claimed agent, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claims 1, 5, 6, and 11 are deemed properly rejected.

Claim Rejections - 35 USC § 102

The rejection of claims 1-10 under 35 U.S.C. 102(b) as being anticipated by Niewohner et al., (WO 01/47928; 2001), English language equivalent U.S. Patent No. 6,803,365 is maintained and applies to claims 1, 5, and 6.

Applicant argues that Niewohner et al. is no longer anticipatory since the claims have been amended such that the reference does not teach a disease of the amended claims. However, the reference teaches treatment of dementia and Alzheimer's disease (see col. 12 lines 33-38). Treating these diseases would inevitably treat age-associated memory loss, for example, since Alzheimer's disease is recognized as the most common degenerative dementia, and the diagnostic criteria for Alzheimer's is progressive worsening of memory and other cognitive functions onset between ages 40 and 90.[1]

Claim Rejections - 35 USC § 103

The rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Niewohner et al., (*supra*) is maintained and applies to claims 1, 5, 6.

Niewohner et al., taught above, differs does not explicitly teach dementia associated with Lewy bodies, for example.

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[1] See Greicius et al., "Presenile dementia syndromes: an update on taxonomy and diagnosis." J. Neurol. Neurosurg. Psychiatry 2002:72; at 692.

However, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to use the compound of Niewohner to treat dementia associated with Lewy bodies since Niewohner claims treatment of dementia in general and the artisan would reasonably expect success in treating more specific forms of dementia such as dementia associated with Lewy bodies, since this is a well known form of dementia.[2] "[W]hen there is a motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1390.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niewohner et al., (*supra*) in view of Dinter et al., (Journal of Molecular Medicine 1997).

Niewohner et al., teaches that the compounds of their invention are useful in treating diseases which are connected with cGMP-regulated processes.

Niewohner et al., differs from the instant claim 11 insofar as it does not disclose treating Multiple Sclerosis (MS).

However, it would have been obvious to use the compounds of Niewohner et al. to treat MS since MS is a disease which is connected with cGMP-regulated processes. Dinter et al., teaches that MS treatment is related to the inhibition of phosphodiesterase, which modifies the duration and extent of signaling initiated through

[2] See Id. at pg. 691 (right column).

cAMP/cGMP-dependent second-messenger pathways. (See Abstract and Phosphodiesterase type IV at pg 96.) The compounds of Niewohner also act through inhibition of phosphodiesterase. Therefore, the artisan would reasonably expect success in using the compounds of Niewohner in the treatment of MS, especially since the treatment method for MS taught in the prior art corresponds with the mechanism of action of the compounds of Niewohner and the prior art recognizes MS as a disease connected with cGMP-regulating processes.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WALTER E. WEBB whose telephone number is (571)270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter E Webb
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